

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

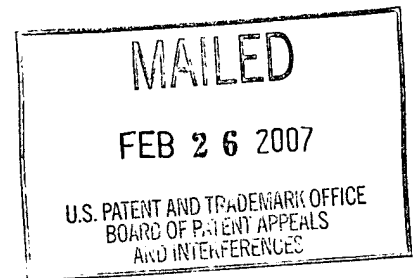
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte DAVID A. CHERESH, ROBERT PAUL
and BRIAN ELICEIRI

Appeal No. 2006-2889
Application No. 09/538,248

HEARD: November 15, 2006



Before GRIMES, GREEN, and LEOVITZ, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-4, 17-20, 32, and 33, all of the pending claims. Claims 1 and 17 are the independent claims on appeal, and read as follows:

1. A method for ameliorating tissue damage related to vascular leakage or edema comprising contacting said tissue with a vascular permeability modulating amount of a pharmaceutical composition comprising a human c-Src tyrosine kinase inhibitor.

17. An article of manufacture comprising packaging material and a pharmaceutical composition contained within said packaging material, wherein said pharmaceutical composition is capable of modulating vascular permeability increase in a tissue suffering from a disease condition, wherein said packaging material comprises a label which indicates that said pharmaceutical composition

can be used for treatment of vascular leakage or edema associated disease conditions, and wherein said pharmaceutical composition comprises a human c-Src tyrosine kinase inhibitor and a pharmaceutically acceptable carrier therefor.

Claims 1, 2, 17, and 18 stand rejected under 35 U.S.C. § 102(e) as being anticipated by the Calderwood patent¹ as evidenced by Burchat 2000,² the Calderwood application³ as evidenced by Burchat 2000, and Hirst⁴ as evidenced by Burchat 2002.⁵ In addition, claims 3, 4, 19, 20, 32, and 33 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of the Calderwood patent, the Calderwood application, Hirst and Hanke.⁶ After careful review of the record and consideration of the issues before us, we affirm the rejection of claims 1, 2, 17 and 18 under 35 U.S.C. § 102(e) as being anticipated by the Calderwood patent as evidenced by Burchat 2000. Because we affirm that rejection, we decline to reach the merits of the other rejections under 35 U.S.C. § 102(e). We also affirm the rejection of claims 3, 4, 19, 20, 32 and

¹ Calderwood et al. (Calderwood patent), US Patent No. 6,001,839, issued December 14, 1999.

² Burchat et al. (Burchat), "Pyrrolo[2,3-*d*]pyrimidines Containing an Extended 5-Substituent as Potent and Selective Inhibitors of Ick II," Bioorganic & Medicinal Chemistry Letters, Vol. 10, pp. 2171-2174 (2000).

³ Calderwood et al. (Calderwood application), US 2003/0187001 A1, published October 2, 2003.

⁴ Hirst et al. (Hirst), US 2002/156081 A1, published October 24, 2002.

⁵ Burchat et al. (Burchat 2002), "Pyrazolo[3,4-*d*]pyrimidines Containing an Extended 3-Substituent as Potent Inhibitors of Lck – a Selectivity Insight," Bioorganic & Medicinal Chemistry Letters, Vol. 12, pp. 1687-90 (2002),

⁶ Hanke et al. (Hanke), "Discovery of Novel, Potent, and Src Family-selective Tyrosine Kinase Inhibitor: Study of Lck and FynT-Dependent T Cell Activation," The Journal of Biological Chemistry, Vol. 271, No. 2 pp. 695-701 (1996).

33 as being obvious over the combination of the Calderwood patent, the Calderwood application, Hirst and Hanke.

DISCUSSION

Claims 1, 2, 17 and 18 stand rejected under 35 U.S.C. § 102(e) as being anticipated by the Calderwood patent as evidenced by Burchat 2000.

As appellants do not argue the claims separately, we focus our analysis on the broadest claim, claim 17. See In re Dance, 160 F.3d 1339, 1340 n.2, 48 USPQ2d 1635, 1636 n.2 (Fed. Cir. 1998) (noting that dependent claims not argued separately on the merits rise or fall with the independent claim to which they relate).

The Calderwood patent is cited for teaching “methods of treating diseases including VEGF mediated edema using tyrosine kinase inhibitors” of specified structure. Examiner’s Answer, page 4. Specific compounds disclosed by the Calderwood patent include 7-isopropyl-5-(4-phenoxyphenyl)-7H-pyrrolo[2,3-d]pyrimidin-4-ylamine (col. 9, lines 7-8), 5-[4-(4-aminophenoxy)phenyl]-7-tert-butyl-7H-pyrrolo[2,3-d]pyrimidin-4-ylamine (col. 9, lines 32-33), and 5-[4-(3-aminophenoxy)phenyl]-7-tert-butyl-7H-pyrrolo[2,3-d]pyrimidin-4-ylamine (col. 9, lines 34-35). See Examiner’s Answer, page 5. The Calderwood patent teaches that Src kinases are among the tyrosine kinase inhibitors that may be inhibited by the disclosed compounds. See id. The Calderwood patent also teaches the manufacture of pharmaceutical compositions containing the compounds of the invention, such as tablets and capsules comprising one of the disclosed compounds, such as those listed above, along with lactose, which is a

pharmaceutically acceptable carrier. See Calderwood, col. 36, Example A, and also see claim 25. The Burchat 2000 reference is cited as evidence that the above recited compounds are src kinase inhibitors. See id. Thus, the examiner asserts that the Calderwood patent anticipates claims 1, 2, 17, and 18.

It is axiomatic that in order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. See In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1432 (Fed. Cir. 1997). We find that the Calderwood patent teaches all of the limitations of claim 17, and the rejection is affirmed.

All that is required by claim 17 is a human c-Src tyrosine kinase inhibitor, a pharmaceutically acceptable carrier, and packaging material. Note that while the claim states that the “packaging material comprises a label which indicates that said pharmaceutical composition can be used for treatment of vascular leakage or edema,” the written material on the label is not a patentable limitation for the claimed composition. See In re Ngai, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004) (where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the substrate, the content of the printed matter will not distinguish the claimed product from the prior art). Thus the issue becomes does Calderwood disclose a human c-Src tyrosine kinase inhibitor.

Appellants argue that Calderwood “does not teach or suggest activity against human c-Src for the disclosed compounds.” Appeal Brief, page 4 (emphasis in original). Appellants argue further that Burchat 2000 was published

after the priority date of the instant application. See id. at 5. According to Appellants, there are many different types of “src” kinases, and there is no indication in Burchat which “src” was used to obtain the data.

First, Burchat 2000 is only cited by the examiner as evidence that the compounds disclosed by Calderwood have the inherent property of being inhibitors of src tyrosine kinase, thus it is irrelevant that the reference was published after the filing date of the instant application. See, e.g., In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). (“When the claimed compositions are not novel they are not rendered patentable by recitation of properties, whether or not these properties are shown or suggested in the prior art.”). As noted by the examiner, Burchat 2000 in Table 2 demonstrates that the compounds 7-isopropyl-5-(4-phenoxyphenyl)-7H-pyrrolo[2,3-d]pyrimidin-4-ylamine, 5-[4-(4-aminophenoxy)phenyl]-7-tert-butyl-7H-pyrrolo[2,3-d]pyrimidin-4-ylamine, and 5-[4-(3-aminophenoxy)phenyl]-7-tert-butyl-7H-pyrrolo[2,3-d]pyrimidin-4-ylamine are src kinase inhibitors. See Examiner’s Answer, pages 12-13.

As also acknowledged by the examiner, while Burchat 2000 fails to specifically state that human src kinase was being used, Burchat 2000 was using human lck, human kdr and tie, and therefore, the reasonable inference is that Burchat is using human c-src, or that the results obtained with the src would have been reasonably expected to predict a compound’s activity on human src.

See id. at 13. Thus, we find that Calderwood teaches compounds that are human c-src inhibitors.

Claims 3, 4, 19, 20, 32 and 33 stand rejected under 35 U.S.C. § 103(a) as being patentable over the combination of the Calderwood patent, the Calderwood application, Hirst and Hanke.

As appellants do not argue the claims separately, we focus our analysis on claim 19.

Claim 19 is dependent on claim 18, which is dependent on claim 17, which is reproduced above. Claim 18 adds the limitation that the human c-Src inhibitor is a chemical inhibitor. Claim 19 reads as follows:

An article of manufacture of claim 18 wherein said human c-Src tyrosine kinase inhibitor is selected from the group consisting of pyrazolopyrimidine PP1, pyrazolopyrimidine PP2, PD173955, PD162531, Radicol R2146 and Geldanamycin.

Thus all that is required by claim 19 is one of the listed compounds, such as PP1, a pharmaceutically acceptable carrier, and packaging material.

As acknowledged by appellants, Hanke discloses that PP1 and PP2 are src kinase inhibitors. See Appeal Brief, page 9; see also Hanke, page 699. Moreover, as noted by the examiner, it would have been obvious to one of ordinary skill in the art at the time the invention was made to package the src inhibitors, PP1 and PP2, into a pharmaceutical composition including the drugs, PP1 or PP2, and a pharmaceutically acceptable carrier, as Hirst teaches that PP1 and PP2 are useful for treatment of conditions such as cancer and osteoporosis. The inclusion of a pharmaceutical composition in a package along

with printed material describing its use is well known in the art and does not define a patentable feature of the composition. See Examiner's Answer, pages 10-11. The examiner also notes, citing Ngai, that what the printed matter states does not constitute a patentable limitation.

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993) (citations omitted). The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). We conclude that the examiner has set forth a prima facie case of obviousness as to claim 19, and the rejection is affirmed.

As set forth by the examiner, the combination of references suggests an article of manufacture comprising PP1 or PP2, a pharmaceutically acceptable carrier for the PP1 and PP2, and packaging material. Moreover, as noted by the specification, PP1 was obtained from Biomol, on license from Pfizer, and PP2 was obtained from Calbiochem, also on license from Pfizer. See Specification, page 33. Thus, PP1 and PP2 are commercially available from companies such as Biomol and Calbiochem, also demonstrating the obviousness of the claimed article of manufacture of claim 19.

Appellants argue that Ngai is distinguishable, as the prior art in that case already taught the kit and the necessary components. See Appeal Brief, page

10. According to appellants, “[t]he new printed matter unquestionably conveys new utility, a new feature, to the package, not previously known to one of ordinary skill in the art.” Id.

Appellants’ argument is not found to be convincing. The only function that that the printed material, i.e., the label required by claims 17 and 19, serves is to indicate that the pharmaceutical composition can be used for treatment of vascular leakage or edema associated disease conditions. Thus, as in Ngai, “the printed matter in no way depends on the kit [i.e., the pharmaceutical composition], and the kit does not depend on the printed matter. All that the printed matter does is teach a new use for an existing product.” Ngai, 367 F.3d at 1339, 70 USPQ2d at 1864 (emphasis added). The compounds PP1 and PP2 are known compounds, and as established by the prior art, the packaging of those known compositions with a pharmaceutically acceptable carrier would have been obvious to the ordinary artisan. If we were to accept appellants’ argument, “anyone could continue patenting a product indefinitely provided that they add a new instruction sheet to the product.” Id. That is clearly not a result envisioned by the court in Ngai, and the rejection is affirmed.

OTHER ISSUES

If prosecution on this application is resumed, the examiner may wish to consider whether claims 1, 2, 17, and 18 are supported by adequate written description.

In Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 63 USPQ2d 1609 (Fed. Cir. 2002), the Federal Circuit adopted a portion of the Guidelines

proffered by the United States Patent and Trademark Office (USPTO). The court stated that:

The written description requirement can be met by “showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of characteristics.”

Enzo Biochem, 323 F.3d at 964, 63 USPQ2d at 1613 (citing Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1 “Written Description Requirement, 66 Fed. Reg. 1099, 1106 (January 5, 2001)).

In University of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 69 USPQ2d 1886, (Fed. Cir. 2004) the Court of Appeals for the Federal Circuit held that claims drawn to methods of inhibiting prostaglandin H synthase-2 (PGHS-2) activity by administering a non-steroidal compound that inhibits activity of PGHS-2 were invalid for failing to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. See 358 F.2d at 917-18, 69 USPQ2d at 1887-88.

The University of Rochester court made clear that cases such as Enzo do not apply only to claims to genetic material, making clear that the written description requirement applies to all types of inventions. See 358 F.2d at 925, 69 USPQ2d at 1893-94. Moreover, while disclosure of a DNA sequence may support claims to complementary molecules that can hybridize to it due to the complementarity of genetic material, “[t]he same is not necessarily true of the chemical arts more generally.” See id. Thus, “[a] description of what a material

does, rather than that of what it is, normally does not suffice.” See 358 F.2d at 923, 69 USPQ2d at 1892 (citation omitted).

Claim 1 is drawn to:

A method for ameliorating tissue damage related to vascular leakage or edema comprising contacting said tissue with a vascular permeability modulating amount of a pharmaceutical composition comprising a human c-Src tyrosine kinase inhibitor.

The claim encompasses a broad range of compounds, wherein the compounds are described only by function, i.e., wherein the compound comprises “a human c-Src tyrosine kinase inhibitor.”

The specification teaches:

A suitable Src family tyrosine kinase inhibitor for purposes of the present invention is a chemical inhibitor selected from the group consisting of PP1, PP2, PD173955, AGL1872, PD162531, Radicicol R2146, and Geldanamycin. Other chemical inhibitors of Src family tyrosine kinases are also appropriate for use in the methods of the invention.

Id. at 5.

Claim 1, however, is not limited to a chemical inhibitor. See claim 2, which specifies the inhibitor is a chemical inhibitor. Thus claim 1 encompasses a huge diversity of molecules, such as proteins, antibodies, DNA, RNA, as well as chemical inhibitors. As to the chemical inhibitors, the disclosure does not set forth any structural relationship between the classes of the compounds that may be used as the therapeutic compound and the claimed therapeutic result, i.e., ameliorating tissue damage related to vascular leakage or edema. The broad classes of compounds useful in the claimed therapeutic methods are thus only described by function.

CONCLUSION

The rejection of claims 1, 2, 17 and 18 under 35 U.S.C. § 102(e) as being anticipated by the Calderwood patent as evidenced by Burchat 2000, is affirmed. Because we affirm that rejection, we decline to reach the merits of the other rejections under 35 U.S.C. § 102(e). We also affirm the rejection of claims 3, 4, 19, 20, 32 and 33 as being obvious over the combination of the Calderwood patent, the Calderwood application, Hirst and Hanke.

Finally, we have raised another issue that the examiner may wish to address upon return of the application.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED



Eric Grimes
Administrative Patent Judge



Lora M. Green
Administrative Patent Judge



Richard M. Lebovitz
Administrative Patent Judge

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OLSON & HIERL, LTD.
20 NORTH WACKER DRIVE
36TH FLOOR
CHICAGO IL 60606